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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,842

07/03/2003

Daryl E. Anderson

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6766

22879 7590 03/21/2007

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EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/613,842	ANDERSON ET AL.	
	Examiner	Art Unit	
	Michael G. Bogart	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 33-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

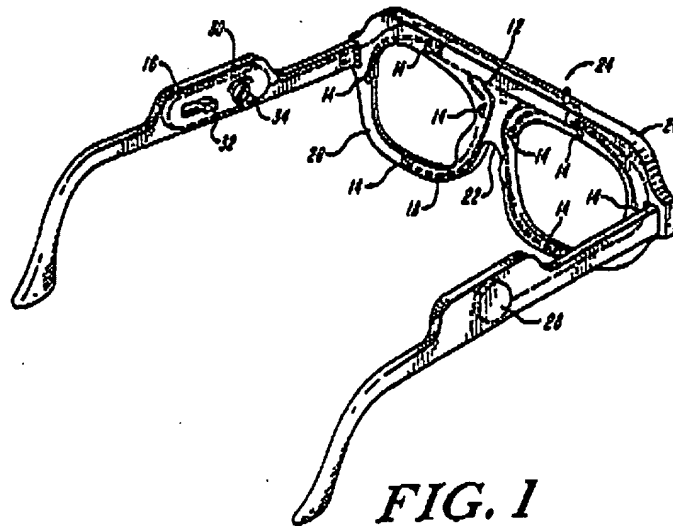
Claims 1-4, 6, 17, 18, 28 and 30-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-50 of copending Application No. 10/412,057. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '057 application claims every material limitation of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-50 of copending Application No. 10/412,057 in view of Bertera (US 5,368,582 A).

The '057 application claims every material limitation of the instant invention except for a spectacle style frame to hold the device in place.

Bertera teaches a spectacle style frame that includes means for introducing fluid to the eyes of a wearer (see figure 1, *infra*).



At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the frame member of Bertera with the dispensing mechanism of the '057 application in order to provide a means for holding the mechanism in place in front of a wearer's eyes.

This is a provisional obviousness-type double patenting rejection.

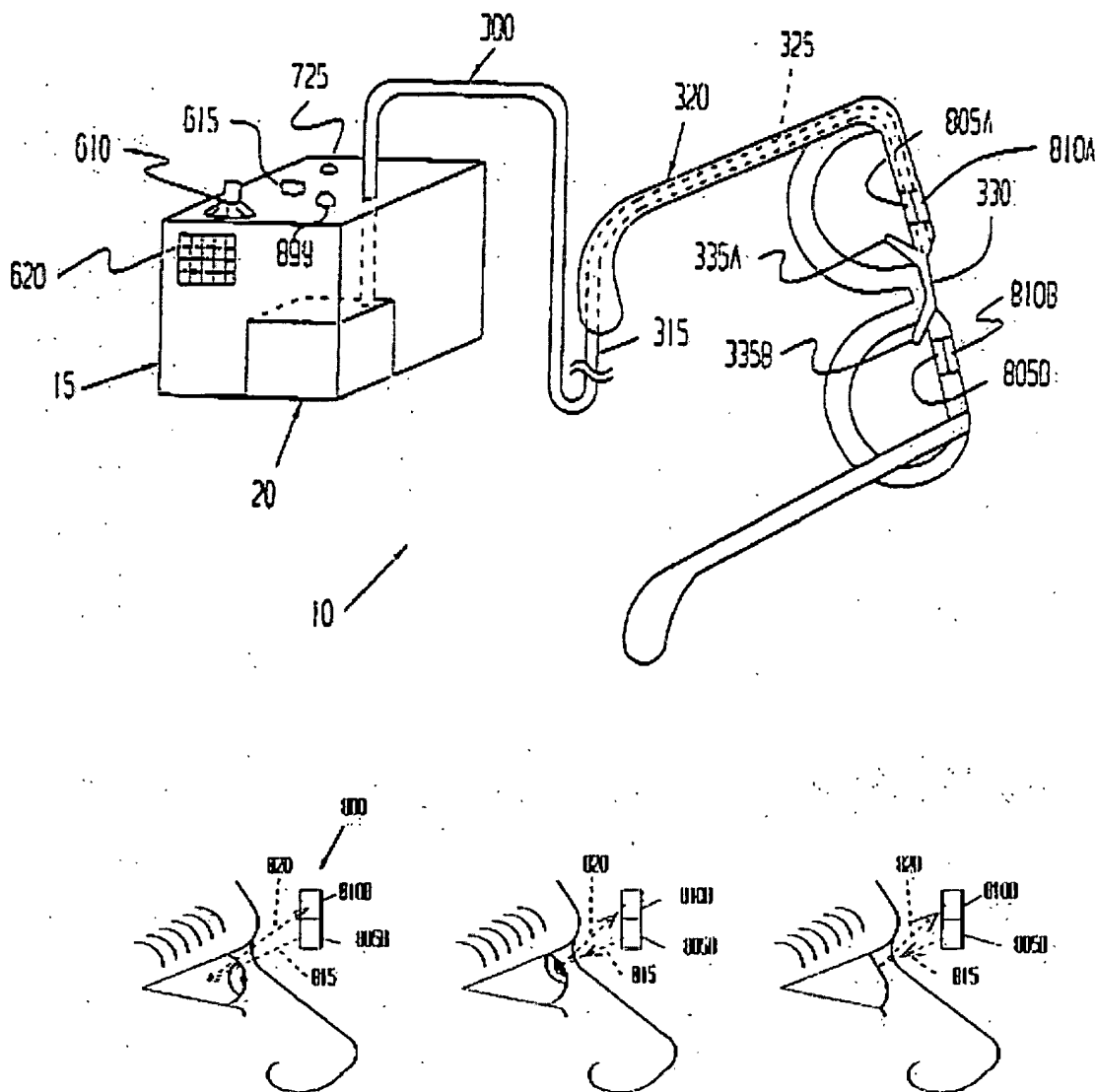
Claims 20 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-50 of copending Application No. 10/412,057 in view of Vo (US 5,171,306 A). The '057 application claims every material limitation of the instant invention except for a detector capable of detecting the position of an eye relative to a dispenser and a spectacle style frame to hold the device in place.

Vo teaches a spectacle frame style eye drop delivery system (10) that detects an eyes position relative to a dispensing apparatus (320)(col. 8, line 65-col. 9, line 30)(see figures 1 and 6A-6C, infra). This permits dispensing of eye drops only when the eye is positioned in a disadvantageous position.

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At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the frame member and eye position detection means of Vo with the dispensing mechanism of the '057 application in order to provide a means for holding the mechanism in place in front of a wearer's eyes and to avoid dispensing of eye drops when the eye is positioned in a disadvantageous position..

This is a provisional obviousness-type double patenting rejection.



***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

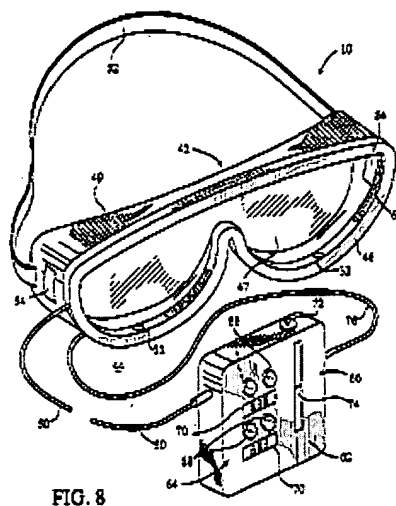
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-10, 14-16, 18, 19 and 28-31 are rejected under 35 U.S.C. § 102(b) as being anticipated by Yee (US 6,270,467 B1).

Regarding claims 1, Yee teaches an eye-positioning device (10) capable of assisting a subject in positioning an eye (2)(to an open or closed position of the eye; also, the visual indicator on the monitor (6) can be used to draw a patient's focus); and

An applicator capable (60, 66, 75, 76) of dispensing fluid into an eye (2)(see figures 8 and 11, infra).



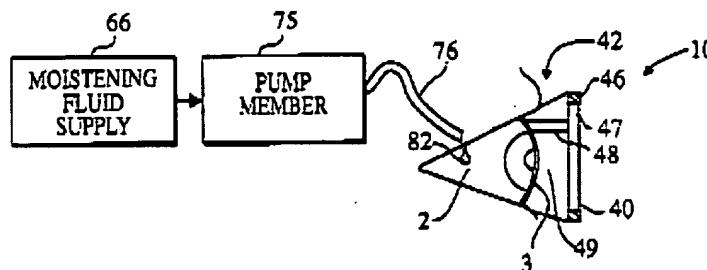


FIG. 11

Regarding the functional limitations, apparatus claims must be structurally distinguishable from the prior art. MPEP § 2114.

Regarding claim 2, Yee teaches an eye position detector (16)(detects whether eye is in open or closed position) and a feedback device (30, 32, 34, 36).

Regarding claim 28, Yee teaches a dispensing means (66, 75, 76).

Regarding claims 3, 4, 30 and 31, Yee teaches a feedback device that provides audible or visual cues (30, 32, 34).

Regarding claim 5, Yee teaches a display monitor (6)(see figure 4, infra). A conventional computer display monitor is capable of displaying an image of an eye.

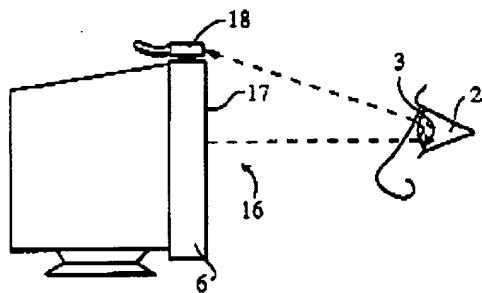


FIG. 4



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Regarding claims 6, and 29, Yee teaches an image pick-up device (16) and an image processor (5, 12, 64).

Regarding claim 8, Yee teaches a feedback device (30, 32, 34, 36) capable of outputting feedback signals to a user.

Regarding claims 9 and 10, Yee teaches a spectacle frame (40) and a fluid dispenser (60) supported by the frame (40)(figure 8).

Regarding claim 14, Yee teaches a controller (64, 90) to actuate the fluid dispenser (60).

Regarding claim 15, Yee teaches that the controller (64, 90) dispenses a predetermined dosage of fluid (82)(col. 12, lines 44-57).

Regarding claim 16, Yee teaches a fluid reservoir (66).

Regarding claim 18, Yee teaches a user interface (5, 68) that can be programmed to set the operating parameters of the apparatus (10).

Regarding claim 19, Yee teaches a graphical interface (6, 70).

### ***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 11-13, 17 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yee as applied to claims 1-6, 8-10, 14-16, 18, 19 and 28-31 above, and further in view of Bertera.

Yee does not disclose expressly that the dispenser includes a thermal droplet jet dispenser.

Bertera teaches a spectacle-like device (10) that includes thermal or piezoelectric jet dispensers (14) to apply treating fluid into an eye (col. 5, lines 1-12; col. 9, lines 3-17)(see figure 1, supra).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the jets of Bertera as the dispenser of Yee in order to provide a structure that is known in the art to be suitable for this purpose.

Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Yee as applied to claims 1-6, 8-10, 14-16, 18, 19 and 28-31 above, and further in view of Miwa (US 6,299,305 B1).

Yee does not expressly disclose that the image pick-up device is a CCD camera.

Miwa teaches an ophthalmic apparatus that uses a CCD camera (10) to detect the dryness of an eye.

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At the time of the invention, it would have been obvious to employ a CCD camera as taught by Miwa as the image capture device of Yee in order to provide an image capture device that is known in the art to be suitable for capturing diagnostic images in a medical setting.

Claims 20, 22 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yee as applied to claims 1-6, 8-10, 14-16, 18, 19 and 28-31 above, and further in view of Vo.

Yee does not expressly disclose an eye position detector that detects an eye position relative to the dispensing apparatus.

Vo teaches a spectacle frame style eye drop delivery system (10) that detects an eyes position relative to a dispensing apparatus (320)(col. 8, line 65-col. 9, line 30)(see figures 1 and 6A-6C, *infra*). This permits dispensing of eye drops only when the eye is positioned in a disadvantageous position.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the frame member and eye position detection means of Vo with the dispensing mechanism of Yee in order to provide a means for holding the mechanism in place in front of a wearer's eyes and to avoid dispensing of eye drops when the eye is positioned in a disadvantageous position.

Claims 24-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yee and Vo as applied to claims 1-6, 8-10, 14-16, 18-20, 22, 23 and 28-31 above, and further in view of Wickham *et al.* (US 6,159,186 A; hereinafter "Wickham").

Yee and Vo do not disclose expressly that the image capture device is a digital camera.

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Regarding claims 24 and 25, Wickham teaches an infusion delivery system that employs a digital camera (28) as an image uptake device, and a image processor (34) capable of processing that camera's images (col. 2, line 66-col. 3, line 13).

At the time of the invention, it would have been obvious to employ a digital camera and digital image processing as taught by Wickham as the image capture device of Yee and Vo in order to provide an image capture device that is known in the art to be suitable for capturing diagnostic images in a medical setting.

Regarding claims 26 and 27, Yee teaches a controller (64, 90) which controls a fluid dispenser (60).

### ***Response to Arguments***

Applicant's arguments with respect to claims 20, and 22-27 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claims 1-19 and 28-32, applicant's arguments filed 18 December 2006 have been fully considered but they are not persuasive.

Regarding claims 1 and 7, applicants assert that Yee does not disclose an eye-positioning device for assisting a subject in positioning an eye. This argument is not persuasive because the device of Yee assists a user in moving their eye from an open to a closed position that occurs during blinking of the eye. Control member (64) serves as both the blink signal (32)(eye open/closed position) monitor and nebulizer controller, permitting a user of the device to only activate the nebulizer when the eye is in an open position.

Regarding claims 2 and 28, applicants assert that Yee eye position detector. This argument is not persuasive because Yee teaches a blink monitor which determines if the eye is in an opened or closed position. It permits a user to move their eye to a closed position during a blink once the signal is provided to the user.

Regarding claims 6 and 29, applicants assert Yee does not disclose a recited image pick-up device, and that Yee's phototransistor measures only light intensity, which is a coarse measurement compared to an image capture. This argument is not persuasive because although the phototransistor of Yee may not capture the full spectrum of light and color visible to the human eye, it is capable of capturing an image of light reflected off an eye.

Regarding claims 8, 11-13, 17 and 30-32, applicants assert that Yee does not disclose a feedback device corresponding to directions for moving an eye to a desired position. This argument is not persuasive because Yee teaches a light that signals a user to blink, which entails moving their eye to the closed position.

Regarding the double patenting rejection over the '057 application, applicants assert that claims 2-50 of the '057 application are directed to a device for administering material to an eye that includes a blink detector. Applicants further assert that acclaims 2-50 of the '057 application do not disclose an eye-positioning device for assisting a subject in positioning an eye. This argument is not persuasive because claims 2-50 of the '057 application are directed to a device that assists a user in moving their eye from an open to a closed position that occurs during blinking of the eye. Control member (64) serves as both the blink signal (32)(eye open/closed position) monitor and nebulizer controller, permitting a user of the device to only activate the nebulizer when the eye is in an open position.

Regarding claims 9-16, applicants assert that claims 2-50 of the '057 application do not teach an eye position detector. This argument is not persuasive because Yee teaches a blink monitor which determines if the eye is in an opened or closed position. It permits a user to move their eye to a closed position during a blink once the signal is provided to the user.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

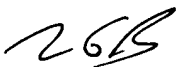
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart  
16 March 2007

**TATYANA ZALUKAEVA**  
**SUPERVISORY PRIMARY EXAMINER**

